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EXAMINER	
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1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,362	PARSONS, DIANA J.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23-29 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *21, 23-29 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, amendment to claims, specification, substitute drawing and response all dated 8-28-08 is acknowledged.

Claims 1-20, 22 and 30-32 have been canceled and Claims 21, 23-29 and 33-37 are pending in the instant application.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-28-08 has been entered.

Examiner notes that the claims submitted by the present amendment is of the same scope as that filed on 11-22-06 except for the specific limitations of pulse duration, fluence and wavelength of the laser light. The specific limitations of pulse duration, fluence and wavelength of the laser light of instant claim 21 were presented in claim 28 of the amendment dated 11-22-06.

In response to the amendment to the specification presented on 8-28-08, deleting the matter added to the specification ""As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)", the previous rejections of record have been replaced with the following rejections:

Specification

The amendment filed on 6/22/07 is no longer present. However, the specification still contains the new matter added by the amendment of 1/7/08, which necessitates new grounds of rejection as follows:

The amendment filed on 1/7/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The entire added text (underlined portion) is considered new matter for the following reasons: The examiner notes that applicant "cuts and pastes" portions of Tankovich's process into the instant process spanning page 6 to 7. It appears applicant is attempting to simultaneously include and exclude certain portions of Tankovich's process. However, the originally field specification clearly states that Tankovich's process is "incorporated by reference". Applicant has amended the specification to recite Tankovich's process (while removing the reference to Tankovich's disclosure on page 7 and only retains it on page 5 of the instant disclosure) between applicant's process. For instance, applicant has inserted "is to irradiate the skin surface with Nd:YAG laser pulses of about 3 J/cm2 at a wavelength of 1.06 micrometers. Pulse frequency is about 5 Hz but we scan the beam so that each location is subjected to pulses at a frequency of about 1 Hz" before applicant's disclosure "for the creation of a chronic wound selectively in the high dermis."

Second, it is noted that applicant has pieced together Tankovich's process. When a reference is incorporated by reference, applicant cannot "re-formulate" the disclosure of the referenced patent. For instance, applicant has inserted the disclosure of column 5, line 42-49 into column 4 of Tankovich's process. Tankovich does not disclose the recited portion, "The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated. For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies" on column 4 after "the particles explode violently ripping off the dead cells of the stratum corneum which lay above the exploding cells." The disclosure of column 5 ("The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated. For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies") is limited to hair removal and does not relate to column 4 which is directed to Pulse Irradiation. Applicant cannot merge the columns together. The recitation, "For hair removal, the beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies" is also pieced together. Therefore, although it is noted

that US 6,036,684 is incorporated by reference, the amendments to the specification are considered new matter for the reasons discussed above. Applicant is required to cancel the new matter in the reply to this Office Action.

In addition to the new matter rejection above (of record as of 3-20-08), the discussion put forward by the previous examiner on pages 2-3, pertaining to deletion of the word "stratum corneum" from the specification, has been maintained.

Examiner notes that applicants have once again argued on page 7 of their response that the removal of "stratum corneum" was in error, which was addressed in detail throughout the prosecution history. In this regard, the declaration provided by applicant on 8-28-08 has been fully considered but not found persuasive. Applicant declares that the ordinary and reasonable meaning of this language (of step 43 in fig 3) is that when the particles are made to explode by the laser light, they disappear and one can see the skin that was underneath the particles before they were made to explode (see Applicant's declaration). This would be the obvious meaning to one of ordinary skill in the art. In order to eliminate any possible confusion, step 43 in Fig. 3 has been amended to remove the phrase "and reveal the underlying skin" without prejudice or disclaimer. However, instant claims as well as the specification are now broader in the sense of the number of pulses of laser light employed and applicants provide evidence in the form of the teachings of Tankovich (also incorporated by reference) that at about 3 pulses that skin is removed. Hence applicants by way of incorporating the teachings of Tankovich admit that the instant treatment results in removing stratum corneum because the instant laser treatment employs the same method of Tankovich.

However, since the instant claims have been now amended to delete the limitations of "one or two pulses" and "with one or two pulses of said laser light does not remove skin or hair", the arguments regarding the enablement put forward on pages 3-5 (of the office action 3-2-08) by the previous examiner have been withdrawn.

Further, in response to the claim amendment, the following rejections of 3-20-08 (pages 8-12) have been withdrawn:

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 21, 23-29, 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The previous office action stated that upon cancellation of the new matter, the following rejection will be reinstated:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21,23-29, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:YAG laser, J Cutan Laser Ther. 1999:1:23-27) in view of in view of Alster (Combined Laser Resurfacing and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12), 1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883).

Goldberg et al teach nonablative skin resurfacing using 1064-nm Q-switched Nd:YAG laser potentiated by a carbon solution at a fluence of 2.5J/cm, repetition rate of 1-10 HZ, and a pulse duration of 6-20ns to treat rhytides (wrinkles). The treatment sites were treated at 4 and 8 weeks. Improvement in wrinkles, skin texture, and elasticity was seen. See abstract. Goldberg does not teach the application of retinoic acid.

Alster teaches cutaneous laser resurfacing recently has advanced the treatment of facial rhytides (wrinkles) to provide a youthful look. Combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides. See abstract. Alster teaches the benefits of tretinoin emollient cream in the treatment of photodamage have been increasingly recognized during the past several years. Although the mechanism of action remains unclear, tretinoin emollient cream has been shown to induce collagen synthesis and decrease the breakdown of collagen, to increase epidermal mucin, to decrease elastosis and epidermal melanin, and to improve organization and promote new synthesis of papillary dermal collagen. The greatest clinical improvements to photodamaged skin with the use

of tretinoin emollient cream have been noted in fine wrinkling, mottled, hyperpigmentation, and skin roughness. See page 41.0.05% applied nightly is disclosed.

Ho et al teach laser resurfacing in pigmented skin and skin with ache scars with a CO2 laser. The method includes: (a) The patients were treated with 0.05% tretinoin, hydroquinone, and desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO2 laser with a setting of 250-450 mJ per pulse, or the Silk-Touch flash scanner at the setting of 5-7 W, 0.2-second pulse duration, and 4-ram (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Ho discloses the reduction of hyperpigmentation with regular use of tretinoin, hydroquinone, and desonide cream both pre- and postoperatively along with use of broad-spectrum sunscreen after treatments. See abstract.

Kye teaches a method of resurfacing pitted facial scars including acne scars, chicken pox scar, and small pox scars, with a pulsed Er:YAG laser. The method includes: step (a) prior to laser surgery, the patients are treated with 0.05% tretinoin (note 0.05% reads on about 0.1%) nightly for two to four weeks; step (b) the patient is then treated with Er:YAG laser at a setting of 500m J/pulse and 3.5-4.5 Watts with a pulse frequency of 7-9 Hz. Kye discloses that after 4-6 laser passes, pinpoint bleeding occurred; step(c) two weeks after laser treatment % tretinoin and 1% hydrocortisone cream is applied for 2-4 weeks. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a pre-treatment and post-treatment regimen prior to the laser therapy taught by Goldberg. One would have been motivated to do so since Alster teaches combining laser resurfacing with long, term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides. Therefore, it is prima facie obvious for a skilled artisan to utilize tretinoin to work in conjunction with laser treatment to provide long lasting results. Further, Ho and Kye both teach the use of tretinoin both pre- and postoperatively. Ho teaches the reduction of hyperpigmentation after laser resurfacing is reduced with regular use of tretinoin, hydroquinone, and desonide cream, both pre-and postoperatively. Thus, Kye and Ho establish the state &the art wherein it is known and conventional to utilize retinoic acid as part of the pre-laser and post-laser regimen, hyperpigmentation. With regard to step (d) in claim 21, Goldberg teaches repeated treatment. Therefore, it is within the skill of an artisan to repeat laser therapy based on the desired result and maintenance for a certain cosmetic condition. For instance, a skilled artisan would be motivated to maintain the treatment as long as required to maintain healthy and young skin including at least once every twelve months or more. It is noted that Goldberg is silent to the number of passes. It appears that the laser is only passed once since Goldberg does not teach passing the laser multiple times. Moreover, the manipulation of the number of laser passes is within the skill of an artisan since it depends on patient parameters. For instance, mild rhytides would only require one pass of the laser. With regard to claim 36, tretinoin is known and routinely used to treat acne

as evidenced by Kye. Therefore, a skilled artisan would have expected the process as claimed in claim 21 to treat acne.

Response to Arguments

Applicants argue as follows:

In Alster's method there is substantial trauma to the skin. Within the first 24 hours after treatment the skin turns bright red, swells, and oozes a clear yellowish liquid. Ice packs and ointments or bandages are prescribed for use. The possible side effects include skin lightening or darkening, infection, acne, scarring, and prolonged redness. After the laser surgery the skin is sensitive and each case must be evaluated continuously.

In Ho's method there is persistent erythema and hyperpigmentation can occur and in Kye's method there is pinpoint bleeding requiring wet gauze treatment. Erythema occurs and is aggravated by the use of retinoic acid.

In Goldberg's method there is removal of skin cells resulting in erythema. In some cases there is pinpoint bleeding. Goldberg states that his procedure is nonablative. Ablation is defined as removal of material from the surface of an object. Thus, Goldberg's method is ablative, although apparently less ablative than those of Alster, Ho, and Kye. Goldberg uses the method of Tankovich as described for hair removal which explodes carbon particles a sufficient number of times to remove skin and produce erythema. All of these above methods remove skin and do not leave the epidermis intact. The prior art teaches that, with laser surgery, some skin must be removed to obtain a beneficial effect on the appearance of the skin. Tankovich teaches

that carbon particles must be exploded a sufficient number of times to remove skin, and that removing skin is necessary to obtain a beneficial effect on the appearance of the skin. Tankovich also teaches that, until that sufficient number of times is achieved, carbon particles can be exploded without removing skin cells. This is shown very clearly in Figures 6 and 7 in US Patent No. 5,423,803, with a corresponding explanation in column 3, lines 30 to 40. A similar description is shown in Figures 3E and 3F in US Patent No. 6,036,684, with a corresponding explanation in column 4, lines 35 to 45. Thus, the prior art teaches that carbon particles can be exploded on the skin in such a way as to leave the epidermis intact, but being ineffective in treating the skin.

Applicants' detailed arguments have been considered but not found persuasive because instant claims (now amended) do not exclude the removal of skin because while the claims fail to explicitly state that the treatment fails to remove the skin, the method claimed allows for more than two or even 3 or 5 pulses of Kye or Goldberg. Accordingly, the above arguments are moot. While instant claims recite that "by itself is ineffective in treating skin" it is not clear what treatment the claims refer to and how they distinguish from the laser therapy of the above references.

The Applicants submit that in order to make a valid rejection based on a prima facie case of obviousness, a combination of references must satisfy the requirements of KSR International v. Tele{lex Inc., 127 S.Ct. 1727,82 USPQ 2d. 1385 (2007). Under the KSR rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third,

the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references. The Applicants respectfully submit that the Examiner has not established prima-facie case of obviousness based on this standard. Applicants arguments are not persuasive because all of the references are directed to improve skin texture and while Goldberg fails to employ tretinoin, each one of Alster, Kye and Ho employ skin treatment for hyperpigmentation, scars or wrinkles (conditions implied by Goldberg) that involves laser treatment and tretinoin.

The exemplary rationales put forward by KSR (above) that support a conclusion of obviousness in the instant case include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Use of known technique to improve similar devices (methods, or products) in the same way

(C) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) " Obvious to try " – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; The

Supreme Court in KSR noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then using the technique would not have been obvious. KSR, 550 U.S. at ___, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The cited prior art clearly provide the above exemplary rationales because the references are in the same field of endeavor and provide the teachings of improved skin conditions with tretinoin in combination with laser therapy. Therefore, it is the examiner's position that replacing the laser method of resurfacing with the exploding particle method of resurfacing in Alster, Ho, and Kye would, therefore, be obvious.

With respect to the argument that the Examiner does not take into account that Applicant's method leaves the epidermis normal and intact (See specification, page 10, line 12), that there is no reason to combine Goldberg with Alster, Ho, and Kye because Goldberg does not leave the epidermis intact because applicant's method of exploding particles, by itself, is ineffective in treating the skin (see Applicant's declaration), while the arguments and the declaration have been considered, instant claims do not recite the argued features

Applicant directs the Examiner's attention to the evidence of such secondary consideration as unexpected results which clearly demonstrate that claim 21 is patentably non-obvious over the combination of cited references, and requests the Examiner to consider this evidence. Applicants refer to the specification on page 9, lines 7-10 state: In the next steps 42 and 43 a laser beam is scanned over the area treated

with the activating solution so as to clean substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. According to the applicants, (page 3, lines 9-10 the specification, declaration) an advantage of the present invention is the production of a chronic wound in the high dermis with no damage to the epidermis. Applicant states in her declaration that a person of ordinary skill in the art would know that exploding the carbon particles to complete the process on the face within about four minutes, leaving the epidermis intact, undamaged, and normal, would require exploding the carbon particles insufficiently to produce any cosmetic or beneficial effect by itself. One of ordinary skill in the art would not reasonably expect the result of skin rejuvenation and improved appearance of the skin by further adding intermittent topical application of retinoic acid to this process of exploding particles on the skin of the face. The prior art would not reasonably predict such a result because there is nothing in the prior art that teaches or suggests that combining retinoic acid with an exploding particle method which by itself is ineffective in treating the skin would produce skin rejuvenation.

However, applicants have not limited their claims to prevent ant skin removal or non-removal and further, applicants do not state how the actual steps of application of laser light is different in the instant versus prior art. Particularly, Goldberg teaches the laser light of same pulses, pulse duration, wave length etc., and applicants merely argue that the method of Goldberg is different from that of the instant without providing any comparison or data. Applicants provide no basis for concluding the nonablative procedure of Goldberg to be ablative.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
December 8, 2008